DT07 Rec'd P TO 0 5 APR 2004

Dkt. 0575/58040-A-PCT-US/JPW/BJA

IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

Applicants : Jonathan M. Barasch et al.

U.S. Serial No.: 09/980,853

Int'l App'l No.

PCT/US00/12536

Entered U.S. National Stage

November 2, 2001

Int'l Filing Date:

May 4, 2000

For :

A METHOD OF INDUCING FORMATION OF KIDNEY

EPITHELIA FROM MESENCHYMAL PRECURSORS

1185 Avenue of the Americas New York, New York 10036

April 2, 2004

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

PETITION TO WITHDRAW HOLDING OF ABANDONMENT IN RESPONSE TO FEBRUARY 24, 2004

NOTIFICATION OF DEFECTIVE RESPONSE ABANDONMENT

This Petition is submitted in response to a Notification Of Defective Response Abandonment issued February 24, 2004 in connection with the above-identified application. A copy of the Notification is attached hereto as **Exhibit A**. A response to the February 24, 2002 Notification is due April 24, 2004. Accordingly, this Petition is being timely filed.

Background

The February 24, 2004 Notification alleges that the applicants failed to properly respond to the January 22, 2002 Notification Of Missing Requirements issued in connection with the above-identified application, a copy of which is annexed hereto as **Exhibit B**. The January 22, 2002 Notification of Missing Requirements indicated that applicants were required to submit a computer readable form Sequence Listing and a Statement in Accordance with 37 C.F.R. §1.821(f) in connection with the above-identified application.

Applicants timely submitted a Communication in Response to January 22, 2002 Notification of Missing Requirements on March 5, 2002. A copy of the return postcard for applicants' March 5, 2002 response, stamped by the Patent Office, and a copy of the response itself, without exhibits, are annexed hereto as Exhibit C. In their March 5, 2002 Communication, applicants noted that a paper copy Sequence Listing and a Statement in Accordance with 37 C.F.R. §1.821(f) had already been submitted by applicants in connection with the aboveidentified application as part of a Preliminary Amendment filed on November 2, 2001. In addition, applicants noted that as part of the same Preliminary Amendment, applicants had requested pursuant to 37 C.F.R. §1.821(e), that the Patent Office use the computer readable Sequence Listing submitted in connection PCT/US00/12536, filed with the U.S. Receiving Office on May 4, 2000. Accordingly, applicants contend that the January 22, 2002 Notification of Missing Requirements erroneously required applicants to submit a Sequence Listing.

However, in order to expedite prosecution, in their response to the January 22, 2002 Notification, applicants included a second request to use the computer readable format Sequence Listing submitted in

connection with PCT/US00/12536, filed with the U.S. Receiving Office on May 4, 2000, and noted that the paper copy Sequence Listing and the Statement in Accordance with 37 C.F.R. §1.821(f) had already been submitted by applicants in connection with the above-identified application as part of a Preliminary Amendment filed on November 2, 2001.

Notwithstanding this second request by applicants, the United States Patent and Trademark Office issued the Notification Of Defective Response Abandonment on February 24, 2004 in connection with the above-identified application. Accordingly, because of the background facts detailed above, applicants contend that the February 24, 2004 Notification of Defective Response Abandonment should not have been issued as the response filed by applicants on March 5, 2002 was in fact complete.

Action Requested

In light of facts presented hereinabove, applicants request that the holding of abandonment be withdrawn and the subject application re-instated.

In addition, applicants hereby again note that the Sequence Listing in the subject application is identical to the Sequence Listing in the parent of the subject application, namely PCT International Application No. PCT/US00/12536, filed May 4, 2000 with the U.S. Receiving Office. However, in order to expedite prosecution, applicants attach herewith copies of the paper copy of the Sequence Listing (3 pages) (Exhibit D) and the Statement In Accordance With 37 C.F.R. §1.821(f) (Exhibit E) previously filed in connection with the above-identified application, and a computer readable form sequence Listing as filed in connection PCT/US00/12536 with as

Exhibit F.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone the number provided below.

No fee is deemed necessary in connection with the filing of this Petition to Withdraw Holding of Abandonment. However, if any such fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

W DIN L

John P. White Reg. No. 28,678 Date

John P. White Registration No. 28,678 Attorney for Applicants Cooper & Dunham LLP 1185 Avenue of the Americas New York, New York 10036 (212) 278-0400



United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address COMMISSIONER FOR PATENTS

P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

U.S. APPLICATION NUMBER NO

FIRST NAMED APPLICANT

ATTY. DOCKET NO.

09/980,853

Jonathan M Barasch

58040-A-PCT-US/JPW/FHB

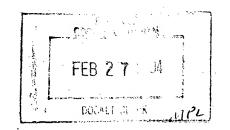
INTERNATIONAL APPLICATION NO. PCT/US00/12536

I.A. FILING DATE

PRIORITY DATE

05/04/2000

John P White Cooper & Dunham 1185 Avenue of the Americas New York, NY 10036



CONFIRMATION NO. 3274 371 FORMALITIES LETTER . .

OC000000011959466

Petition to Revive: 4/24/04 MPL

Date Mailed: 02/24/2004

NOTIFICATION OF DEFECTIVE RESPONSE ABANDONMENT

The United States Patent and Trademark Office in its capacity as a Designated / Elected Office (37 CFR 1.495) has made the following determination:

Applicant has failed to properly respond to the notification of MISSING REQUIREMENTS (Form PCT/DO/EO/905), mailed 01/22/2002 within the time period set therein.

Therefore, the above identified application failed to meet the requirements of 35 U.S.C. 371 and 37 CFR 1.495. and is ABANDONED AS TO THE UNITED STATES OF AMERICA.

The following items MUST be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

The following items MUST be furnished within the period set forth below:

- The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 CFR 1.821-1.825 for the following reason(s):
 - A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 CFR 1.821(e) and PCT Rule 13ter.1(a)(ii).
 - APPLICANT MUST PROVIDE:
 - An initial or substitute computer readable form (CRF) of the "Sequence Listing."
 - A statement that the contents of the paper or compact disc and the computer readable form are the same and, where applicable, include no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b) or 1.825(d).
- For questions regarding compliance to 37 CFR 1.821-1.825 requirements, please contact:
 - For Rules Interpretation, call (703) 308-4216
 - To Purchase Patentin Software, call (703) 306-2600
 - For Patentin Software Program Help, call (703) 306-4119 or e-mail at patin21help@uspto.gov or patin3help@uspto.gov

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

Applicants: Jonathan M. Barasch et al.

U.S. Serial No.: 09/980,853 Filed: November 2, 2001

Exhibit A

LAMONT M HUNTER

Telephone: (703) 305-3686

PART 2 - OFFICE COPY

U.S. APPLICATION NUMBER NO.	INTERNATIONAL APPLICATION NO.	ATTY. DOCKET NO.
09/980,853	PCT/US00/12536	58040-A-PCT-US/JPW/FHB

FORM PCT/DO/EO/918 (371 Formalities Notice)









UNITED STATES PATENT AND TRADEMARK OFFICE

Convenessioner for Pateino, Bon PCI United States Patent and Traditions Office Washington, D.C. 2023

U.S. APPLICATION N	IUMBER NO.	FIRST NAMED APPLICANT	ATT	Y. DOCKET NO.
09/980,8		Jonathan M Barasch	58040-A-	PCT-US/JPW/FHB
		1/22/2002	INTERNATIONAL A	PPLICATION NO.
1.25	1/22/2002	PCT/US00/12536		
	MP Due;	3/22/2002	I.A. FILING DATE	PRIORITY DATE
New York, NY 10036	1/22/2006	05/04/2000	5/4/1905	
	nericas P Evil	5/22/2002	CONFIRM	MATION NO. 3274
	MFENT:	8/22/2002	371 FORMALITIES	

Date Mailed: 01/22/2002

NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as an Elected Office (37 CFR 1.495):

- U.S. Basic National Fees
- Indication of Small Entity Status
- Biochemical Sequence Listing
- Copy of IPE Report
- Copy of the International Application
- Copy of the International Search Report
- Oath or Declaration
- Preliminary Amendménts
- Request for Immediate Examination
- Small Entity Statement

The following items MUST be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- o Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), identifying the application by the International application number and international filing date. The current oath or declaration does not comply with 37 CFR 1.497(a) and (b) in that it:
 - is not executed in accordance with either 37 CFR 1.66 or 37 CFR 1.68.
- The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 CFR 1.821-1.825 for the following reason(s):
 - A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 CFR 1.821(e).
 - APPLICANT MUST PROVIDE:
 - a An initial or substitute computer readable form (CRF) of the "Sequence Listing."

Applicants: Jonathan M. Barasch et al. U.S. Serial No.: 09/980,853

Filed: November 2, 2001 Exhibit B

JAN 29 300





- A statement that the contents of the paper or compact disc and the computer readable form are the same and, where applicable, include no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b) or 1.825(d).
- For questions regarding compliance to 37 CFR 1.821-1.825 requirements, please contact:
 - For Rules Interpretation, call (703) 308-4216
 - To Purchase Patentin Software, call (703) 306-2600
 - □ For PatentIn Software Program Help, call (703) 306-4119 or e-mail at patin21help@uspto.gov or patin3help@uspto.gov

ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTH FROM THE DATE OF THIS NOTICE OR BY 22 or 32 MONTHS (where 37 CFR 1.495 applies) FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

A copy of this notice MUST be returned with the response.

LAMONT M HUNTER

Telephone: (703) 305-3686

PART 1 - ATTORNEY/APPLICANT COPY

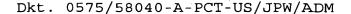
U.S. APPLICATION NUMBER NO.	INTERNATIONAL APPLICATION NO.	ATTY. DOCKET NO.
09/980,853	PCT/US00/12536	58040-A-PCT-US/JPW/FHB

Applicant	Jonathan Barasch et al.	
Client	0575 (COLUMBIA)	File No. 58040-A-PCT-US PROADM
Date	March 5, 2002	All
	Kindly acknowledge	MAR 12 mm C

Communication In Response To January 22, 2002 Notification Of Missal Requirements Under 35 U.S.C. §371 And Information Disclosure for Jonathan Barasch et al., A METHOD OF INDUCING FORMATION OF KIDNEY EPITHELIA FROM MESENCHYMAL PRECURSORS, U.S. Serial No. 09/980,853, filed November 2, 2001, including a copy of the Notification (Exhibit A), signed Declaration and Power of Attorney (Exhibit B), Form PTO-1449 (Exhibit C), a check for \$65.00, and a Certificate of Mailing dated March 5, 2002.

DUE DATE: March 22, 2002 by placing your receiving date stamp hereon and returning to us JC05 Rec'd PC 1/270 1 2 MAR 2002

W.D.



IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

Applicants : Jonathan M. Barasch et al.

U.S. Serial No.: 09/980,853

Int'l App'l No.

PCT/US00/12536

Entered U.S. National Stage

November 2, 2001

Int'l Filing Date:

May 4, 2000

For

A METHOD OF INDUCING FORMATION OF KIDNEY

EPITHELIA FROM MESENCHYMAL PRECURSORS

1185 Avenue of the Americas New York, New York 10036 March 5, 2002

Assistant Commissioner for Patents

BOX PCT

Washington, D.C. 20231

ATTN: DO/EO/US

Sir:

COMMUNICATION IN RESPONSE TO JANUARY 22, 2002

NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. §371 AND INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. §1.97(b)(3)

This Communication is submitted in response to a Notification Of Missing Requirements Under 35 U.S.C. §371 issued January 22, 2002 in connection with the above-identified application. A copy of the Notification is attached hereto as **Exhibit A**. A response to the January 22, 2002 Notification is due March 22, 2002. Accordingly, this Communication is being timely filed.

The Notification indicates that an oath executed in accordance with 37 C.F.R. §1.66 or a declaration executed in accordance 37 C.F.R. §1.68 is required. In response, applicants submit as **Exhibit B** hereto an original signed Declaration and Power of Attorney executed in accordance with 37 C.F.R. §1.68 and in compliance with

37 C.F.R. §1.497(a) and (b). In compliance with 37 C.F.R. §1.497(a), the Declaration refers to the application's above-identified International Application Number, International Filing Date, U.S. Serial Number, and date of U.S. National entry.

The surcharge for submitting the Declaration for a small entity is the SIXTY-FIVE DOLLAR (\$65.00) fee set forth in 37 C.F.R. §1.492(e) and a check in this amount is enclosed.

Sequence Listing

The Notification indicates that a computer readable form (CRF) of the Sequence Listing has not be submitted as required by 37 C.F.R. §1.821(e).

In response, applicants respectfully refer the Examiner to the following paragraph which was included as part of the Preliminary Amendment that was filed when the subject application entered the U.S. National stage on November 2, 2001:

Sequence Listing in the subject application is identical to the Sequence Listing in the parent of the subject application, namely PCT International Application No. PCT/US00/12536, filed May 4, 2000. Applicants attach herewith copies of the paper copy of the Sequence Listing (3 pages) and the Statement In Accordance With 37 C.F.R. which were filed with §1.821(f) PCTInternational Application No. PCT/US00/12536 on May 4, 2000. accordance with 37 C.F.R. §1.821 (e), please use the computer readable form filed in PCT International Application No. PCT/US00/12536 on May 4, 2000 as the

computer readable form for the instant application. It is understood that the Patent and Trademark Office will make the necessary change in application number and filing date for the computer readable form that will be used for the instant application.

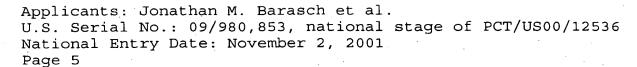
Accordingly, in accordance with 37 C.F.R. §1.821(e), please use the computer readable form filed in PCT International Application No. PCT/US00/12536 on May 4, 2000 as the computer readable form for the instant application.

INFORMATION DISCLOSURE STATEMENT

In accordance with their duty of disclosure under 37 C.F.R. §1.56, applicants would like to direct the Examiner's attention to the following references which are listed on the attached Form PTO-1449 (Exhibit C). These references were previously submitted or cited in connection with the prosecution of U.S. Serial No. 09/305,029. The subject application claims benefit of the filing date of U.S. Serial No. 09/305,029 under 35 U.S.C. §120. According to 37 C.F.R. §1.98(d), copies of patents or publications that were previously cited by, or submitted to, the Patent Office in connection with such prior applications need not accompany the Information Disclosure Statement. Accordingly, copies of the following references are not attached to this Information Disclosure Statement:

1. PCT International Publication No. WO 00/41713, published July 20, 2000;

- 2. Barasch, J., L. Pressler, J. Connor, and A. Malik. 1996. A ureteric bud cell line induces nephrogenesis in two steps by two distinct signals. *Am. J. Physiol*. 271: F50-F61;
- 3. Barasch, J., J. Qioa, G. McWilliams, D. Chen, J.A. Oliver, and D. Herzlinger. 1997. Ureteric bud cells secrete multiple factors, including bFGF, which rescue renal progenitors from apoptosis. Am. J. Physiol. 273: F757-F767;
- 4. Barasch, J., J. Yang, J. Qiao, P. Tempst, H. Erdjument-Bromage, W. Leung, J.A. Oliver. May, 1999. Tissue inhibitor of metalloproteinase-2 stimulates mesenchymal growth and regulates epithelial branching during morphogenesis of the rat metanephros. J. Clin. Invest. 103: 1299-1307;
- 5. Bard, J.B.L. and A.S.A. Ross. LIF, the ES-cell inhibition factor, reversibly blocks nephrogenesis in cultured mouse kidney rudiments. Development 113: 193-198, 1991;
- 6. Boccaccio, C., M. Ando, L. Tamagnone, A. Bardelli, P. Michieli, C. Battistini, and P.M. Comoglio. 1998. Induction of epithelial tubules by growth factor HGF depends on the STAT pathway. *Nature* 391: 285-288;
- 7. Bonni, A., Y. Sun, M. Nadal-Vicens, A. Bhatt, D. A. Frank, I. Rozovsky, N. Stahl, G.D. Yancopoulos, and M.E. Greenberg. 1997. Regulation of gliogenesis in the central nervous system by the JAK-STAT signaling pathway. Science 278: 477-483;
- 8. Grobstein, C. 1955. Inductive interaction in the development of the mouse metanephros. *J. Exp. Zool*. 130: 319-339;
- 9. Gruenwald, P. 1943. Stimulation of nephrogenic tissue by normal and abnormal inductors. *Anat. Rec.* 86: 321-335;
- 10. Hartner, A. et al. Cytokine-induced expression of leukemia inhibitory factor in renal mesangial cells. Kidney International 45: 1562-1571, 1994;
- 11. Hartner, A. et al. Renal mesangial cells have the capacity to synthesize and react to leukemia inhibitory factor. Ann. N.Y. Acad. Sci. 762 (Interleukin-6-Type Cytokines): 424-425, 1995 (Abstract);



- 12. Herzlinger, D., J. Qiao, D. Cohen, N. Ramakrishna, and A.M.C. Brown. 1994. Induction of Kidney epithelial morphogenesis by cells expressing *Wnt-1*. *Develop. Biol.* 166: 815-818;
- 13. Karavanova, I.D., L.F. Dove, J.H. Resau, and A.O. Perantoni. 1996. Conditioned media from a rat ureteric bud cell line in combination with bFGF induces complete differentiation of isolated metanephric mesenchyme. *Development* 122: 4159-4167;
- 14. Kispert, A., S. Vainio, A.P. McMahon. 1998. Wnt-4 is a mesenchymal signal for epithelial transformation of metanephric mesenchyme in the developing kidney. *Development* 125: 4225-4234;
- 15. Mayer, M., Bhakoo, K., and M. Noble. 1994. Ciliary Neurotrophic factor and leukemia inhibitory factor promote the generation, maturation and survival of oligodendrocytes in vitro. Development 120: 143-153;
- 16. Morel, D.S. et al. Renal synthesis of leukemia inhibitory
 factor. Cytokine 12(3): 265-271, 2000 (Abstract);
- 17. Murphy, M., K. Reid, D.J. Hilton, and P.F. Bartlett. 1991. Generation of sensory neurons is stimulated by leukemia inhibitory factor. *Proc. Natl. Acd. Sci.* USA 88: 3498-3501;
- 18. Murphy, M., K. Reid, M.A. Brown, P.F. Bartlett. 1993 Involvement of leukemia inhibitory factor and nerve growth factor in the development of dorsal root ganglion neurons. Development 117: 1173-1182;
- 19. Murphy, M., K. Reid, M. Ford, J. B. Furness, and P. F. Bartlett. 1994. FGF2 regulates proliferation of neural crest cells, with subsequent neuronal differentiation regulated by LIF or related factors. *Development* 120: 3519-3528;
- 20. Perantoni, A.O., L.F. Dove and I. Karavanova. 1995. Basic fibroblast growth factor can mediate the early inductive events in renal development. Proc. Natl. Acad. Sci. USA. 92: 4696-4700;
- 21. Sariola, H., P. Ekblom, S. Henke-Fahle. 1989. Embryonic neurons as *in vitro* inducers of differentiation of nephrogenic mesenchyme. *Devel. Biol.* 132: 271-281;

- 22. Stark, K., S. Vainio, G. Vassileva, A. P. McMahon. 1994. Epithelial transformation of metanephric mesenchyme in the developing kidney regulated by Wnt-4. Nature 372: 679-683;
- 23. Taupin, J.L. et al. HILDA-LIF urinary excretion during acute kidney rejection. Transplantation 53(3): 655-658, 1992 (Abstract); and
- 24. Wallner, E.I. et al. Growth factors in metanephric development. Renal Failure 20(2): 331-341, 1998 (Abstract).

Applicants are submitting this Information Disclosure Statement under 37 C.F.R. §1.97(b)(3) before the mailing of a first Office Action on the merits. Accordingly, no fee is deemed necessary in connection with the filing of this Information Disclosure Statement.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone the number provided below.

Applicants: Jonathan M. Barasch et al. U.S. Serial No.: 09/980,853, national stage of PCT/US00/12536

National Entry Date: November 2, 2001

Page 7

No fee, other than the enclosed \$65.00 surcharge for filing the attached Declaration, is deemed necessary in connection with the filing of this Communication and Information Disclosure Statement. However, if any other fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,

hereby certify that correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant

Commissioner for Patents, BOX PCT, Washington, D.C. 20231.

Alan D. Miller

Req: No. 42,889

John P. White

Registration No. 28,678

Alan D. Miller

Registration No. 42,889 Attorneys for Applicants

Cooper & Dunham LLP

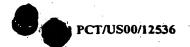
1185 Avenue of the Americas

New York, New York 10036

(212) 278-0400

Date





SEQUENCE LISTING

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Applicants: Jonathan M. Barasch et al. U.S. Serial No.: 09/980,853 Filed: November 2, 2001 Exhibit D

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WO 00/66147



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IN THE UNITED STATES RECEIVING OFFICE (RO/US)

Applicant

The Trustees of Columbia University in the

City of New York

International

Application No.:

Not Yet Known

International

Filing Date

Herewith

For

METHOD OF INDUCING FORMATION OF KIDNEY

EPITHELIA FROM MESENCHYMAL PRECURSORS

1185 Avenue of the Americas New York, New York 10036

May 4, 2000

Honorable Commissioner for Patents

Box PCT

Washington, D.C. 20231

ATTN: RO/US

SIR:

STATEMENT IN ACCORDANCE WITH 37 C.F.R. §1.821(f) FOR ABOVE-IDENTIFIED APPLICATION

Pursuant to 37 C.F.R. §1.821(f), I hereby certify that the contents of the Sequence Listing (3 pages) attached hereto as **Exhibit A** and the contents of the computer readable form of the sequence listings are identical.

Respectfully submitted,

Jennifer H. Burdman

Registration No. 44,574 c/o Cooper & Dunham LLP 1185 Avenue of the Americas New York, New York 10036

(212) 278-0400

Exhibit E